

REMARKS

Upon entry of the foregoing amendments, claims 1-13, 15, 16, 18-27, 29, 37, and 48-51 will be pending. Claims 1, 34 and 36 remain as the only independent claims.

Applicants are pleased to note that there are no prior art rejections. The only objections and rejections relate to asserted new matter having been added to the application specification and to claims 10, 11 and 13 in the Amendment filed February 14, 2005 (the "February 14 Amendment"), to asserted lack of enablement and asserted lack of an adequate written description, and to an asserted indefiniteness of claim 14. Reconsideration and withdrawal of all of the objections and rejections are respectfully requested in view of the foregoing amendments and the following remarks.

The written description in the specification at page 25, lines 10-15, has been amended to return to the original language relating to target cells being a cell of the "unspecific immune system" or a cell of the "specific immune system." Thus, the language added to the specification in the February 14 Amendment, reciting a cell of the unspecific immune system, "known to provide innate immunity," or a cell of the specific immune system, "known to provide acquired immunity" has been deleted. The original language relating to the "unspecific immune system" or the "specific immune system" has also been reinserted in claims 10, 11 and 13, despite the Examiner's statements in Items 4 and 10 of the Detailed Action that he did not find adequate supporting language in the references mentioned in the Langer Declaration accompanying the February 14 Amendment indicating equivalence of unspecific immunity and innate immunity on the one hand, and specific immunity and acquired immunity on the other hand. The undersigned attorney apologizes for not being more specific in pointing out where the equivalence is specifically mentioned in the references.

The Examiner's attention is directed to Kuby, "Immunology" (labeled as Reference 20 when submitted, but identified as Reference 21 in the Langer Declaration's list of references at page 9 of the Langer Declaration. Page 6, right column of Kuby, under the heading "Components of Immunity," states:

Immunity-the state of protection from infections disease-has both nonspecific and specific components. **Innate**, or nonspecific, **immunity** refers to the basic resistance to disease that an individual is born with.

Acquired, or specific, **immunity** requires the activity of a functional immune system, involving cells called lymphocytes and their products. Innate defense mechanisms provide the first line of host defense against invading pathogens until an acquired immune response develops. In general, most of the microorganisms encountered by a healthy individual are readily cleared within a few days by nonspecific defense mechanisms without enlisting a specific immune response. When an invading microorganism eludes the nonspecific host defense mechanisms, a specific immune response then is enlisted. Acquired immunity does not operate independently of innate immunity; rather, the specific immune response supplements and augments the nonspecific defense mechanisms, producing a more effective total response. [Bold emphasis in original; underlined emphasis added]

A section entitled “INNATE (NONSPECIFIC) IMMUNITY” begins at the bottom of page 6 of Kuby and extends through the bottom of page 11. The top of page 12 begins with the heading “ACQUIRED (SPECIFIC) IMMUNITY” that extends to page 22. It is very clear that one skilled in the art would understand that the application’s “specific” immunity means “acquired” immunity. It should be equally clear that the application’s “unspecific” immunity, (unquestionably, “unspecific” would be understood to mean the same thing as “nonspecific”) means innate immunity, in view of the Kuby textbook explanations. In view of this, rather than arguing about retaining the language inserted in the written description and claims 10, 11 and 13 in the February 14 Amendment, it is better to return to the original language of the application as filed, in view of the foregoing explanation, which indicates how one skilled in the art would understand the language used in this application.

Reconsideration and withdrawal of the objections and rejections based on new matter grounds are respectfully solicited.

The Examiner recognized in Item 3 of the Detailed Action that “the instant claims are drawn only to a nucleic acid encoding a fusion protein, a vector, a host cell and a kit, none of which are inherently unpredictable.” However, in Item 6 of the Detailed Action, the Examiner noted: With regards to the instant claims, their breadth comprises a primary factor in establishing the unpredictability of the claimed fusion proteins.” It appears that the Examiner returned to the apparent misunderstanding in prior Office Actions, by several Examiners who have handled this application, about the claimed subject matter – primarily a nucleic acid as noted in Item 3 of the Detailed Action. To the extent that Applicants’ claims are broad, their

breadth is warranted by the lack of prior art cited against them and by the nature of their invention.

Applicants strenuously disagree with the Examiner's conclusions or bases for them that the application does not enable a person skilled in the art to make and use the claimed invention and that the application's written description does not show that Applicants possessed the invention. Nevertheless, to advance the prosecution of this application that has been pending since 1999, and without prejudice to proceeding in one or more related applications that may be filed in the future, Applicants have cancelled claims or amended claims to delete all references to unspecific fragments, substitutions, insertions, additions, exchanges or derivatives.

Claims 1-3, 5, 6, 8, 34, 35, 36 and 37, which had recited such fragments, etc., have been amended to delete all such recitations. Claims 1, 5, 34 and 36, which had also recited various modules based on alternative hybridizations and degenerate nucleic acid molecules, have been amended to delete these recitations, too. The remaining language of these claims is believed to be definite and well-supported by the application as filed, such that it is clear that Applicants were in possession of the claimed invention when the application was filed, and also enables a skilled person to make and use the invention as claimed.

Applicants have cancelled, without prejudice, claim 14, reciting "a degenerate cell of the immune system," rendering moot the rejection of that claim for indefiniteness under 35 U.S.C. § 112, second paragraph (Item 8 of the Office Action). Applicants believe that the invention is adequately covered without this claim. For a similar reason concerning adequate coverage, claims 17 and 47, relating to certain broad recitations of exchanged amino acids, have also been cancelled, without prejudice. Claims 18 and 48, relating to specific substituted amino acids in certain positions, have been amended to incorporate such language from claims 17 and 47, respectively, that they are clear in context without claims 17 and 47. The language "at least one amino acid exchange" used in claims 17 and 47 has not been repeated in claims 18 and 48.

A few other minor amendments relating to syntax, grammar or to correct typographical errors were also corrected as will be apparent when reviewing the claims marked to show the amendments.

New dependent claim 49 has been added and relates to the targeting module being MHC II, as supported by the application as filed, at page 24, lines 2-5.

New claim dependent claim 50 has been added to specifically cover bFGF as the processing module. Claim 50 is supported by the application as filed in the paragraph bridging pages 35 and 36, at least.

New dependent claim 51 has been added to better define the fusion protein encoded by the nucleic acid molecule specifically as bFGF-MLA or bFGF-MLA coupled to rMLB. Claim 51 is supported at least in the paragraph bridging pages 36 and 37, and in Examples 5 and 6 of the application as filed.

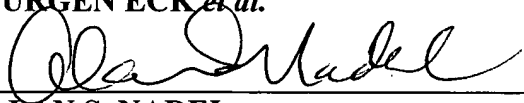
Since no new matter has been added, Applicants respectfully request entry of all of the foregoing amendments.

All of the other concerns of the Examiner are believed to have been addressed, and the application is now believed to be in condition for allowance. Reconsideration and withdrawal of all rejections and objections, and an early Notice of Allowance are respectfully solicited.

If the Examiner believes that there are any remaining issues that could be resolved readily by a telephone discussion, the Examiner is invited to telephone the undersigned attorney.

Respectfully submitted,

JÜRGEN ECK *et al.*

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(Date)

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Enclosure: Petition for Three Month Extension of Time